

NON-GLP STUDY REPORT

STUDY TITLE

Quantitative Evaluation of Air Treatment Efficacy Against Airborne
Bacteria in a Large Indoor Space

Test Organism(s):

Staphylococcus aureus (ATCC 6538)

PRODUCT IDENTITY

VigorOx Liquid Sanitizer and Disinfectant
Lot 17622C1420

TEST DEVICE IDENTITY

V2 Fog Tank, Serial Number 2219

AUTHOR

Thomas Breyen
Senior Virologist

STUDY COMPLETION DATE

May 31, 2023

PERFORMING LABORATORY

Element Materials Technology Eagan
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Pure Maintenance LLC
334 Marshall Way, Suite D
Layton, UT 84041

SPONSOR REPRESENTATIVE

Keller and Heckman LLP
1001 G Street NW, Suite 500 West
Washington, DC 20001

PROJECT NUMBER

A37939

This study was not performed under
EPA Good Laboratory Practice Regulations
(40 CFR Part 160)

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Quantitative Evaluation of Air Treatment Efficacy Against Airborne Bacteria in a Large Indoor Space

Project Number: A37939

TRF Number: PUR006013023.AIRB.1

TEST SUBSTANCE IDENTITY

Test Substance	VigorOx Liquid Sanitizer and Disinfectant, Lot 17622C1420
Test Substance Dilution	19.2 oz/108.8 oz defined as 19.2 oz of test substance + 108.8 oz Deionized Water

TEST PARAMETERS

Delivery Mechanism	V2 Fog Tank
Room Volume/ Dimensions	≤5000 ft ³
Spray Conditions	Device prepared and operated by the Sponsor. Spray duration determined by Sponsor. In testing, spray duration was 8 minutes 50 seconds.
Sample Timepoints	Time zero, 10 minutes, 30 minutes, 45 minutes
Exposure Conditions	18-25°C at 40-60% RH

STUDY DATES

Date Sample Received	May 11, 2023 (Test Device) May 12, 2023 (Test Substance)
Study Initiation Date	May 16, 2023
Experimental Start Date	May 16, 2023
Experimental End Date	May 19, 2023
Study Completion Date	May 31, 2023

TEST ORGANISM

Test Organism	ATCC #	Growth Medium	Incubation Parameters
<i>Staphylococcus aureus</i>	6538	Tryptic Soy Broth	35-37°C aerobic

The test organism(s) used in this study was/were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

INOCULUM PREPARATION

Organism	<i>Staphylococcus aureus</i> ATCC# 6538
Target Time Zero Concentration	10 ⁶ CFU/m ³
Diluent	Deionized Water
Organic Soil Load	Tri-Part Soil
Agar Plate Medium	Tryptic Soy Agar + 5% Sheep's Blood

ENVIRONMENTAL CONDITIONS

Pre-Nebulization Temperature	19.6°C (Baseline) 19.8°C (Test)
Pre-Nebulization Humidity	56.9% (Baseline) 55.4% (Test)
Post-Sampling Temperature	19.7°C (Baseline) 19.0°C (Test)
Post-Sampling Humidity	55.1% (Baseline) 77.9% (Test)
HVAC Status During Nebulization	OFF
HVAC Status During Treatment	OFF
Ceiling Fan Setting During Nebulization	OFF
Ceiling Fan Setting During Treatment	OFF

AIR SAMPLING – SKC Biosampler

Collection Fluid/Neutralizer	PBS
Sample Location	6' at interior wall
Replicates	3 per time point

EXPERIMENTAL DESIGN

Airborne organism was generated from a liquid inoculum using a Collison nebulizer and introduced into the containment lab at a target concentration of 10^6 CFU/m³. The organism was exposed to the test substance using the Sponsor supplied device V2 Fog Tank for the specified exposure time (Determined by Sponsor, 8 minutes 50 seconds in testing). Following exposure, air samples were collected in neutralization fluid and analyzed for survivors. Log reductions are based on time zero value and normalized to account for natural decay of the organism in air. Appropriate neutralization confirmation, background contamination, organism purity, inoculum count, organic soil sterility and neutralization subculture medium sterility controls were performed.

Per Sponsor's direction, the study was not required to be conducted under U.S. EPA 40 CFR Part 160 or U.S. FDA 21 CFR Part 58.

STUDY RESULTS

TABLE 1: RESULTS SUMMARY

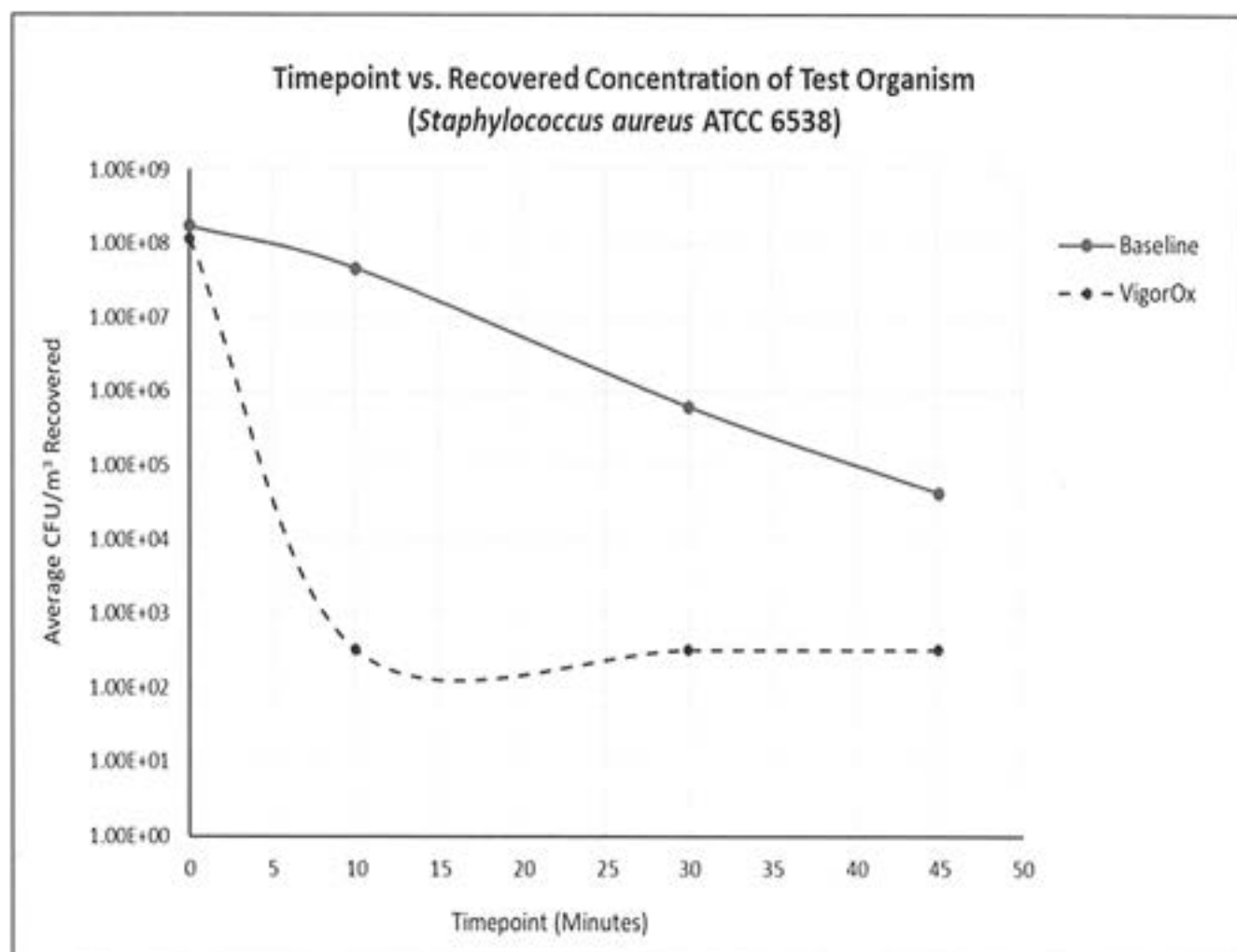


TABLE 2: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control	Results
	<i>Staphylococcus aureus</i> (ATCC 6538)
Purity Control	Pure
Inoculum Count	4.1×10^9 CFU/mL
Neutralizing Subculture Medium Sterility Control	No Growth
Background Contamination Control	No Growth

TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Neutralization Confirmation (CFU)		Percent Recovery	Pass/Fail ≥50%)
		Numbers Control	Results		
VigorOx Liquid Sanitizer and Disinfectant, applied using the V2 Fog Tank	<i>Staphylococcus aureus</i> (ATCC 6538)	22	22	100%	Pass

CFU = Colony Forming Unit

TABLE 4: BASELINE RESULTS

Organism	Timepoint	Average CFU/m ³	Average Log/m ³	Log ₁₀ Decay vs. Time Zero
<i>Staphylococcus aureus</i> (ATCC 6538)	Time Zero	1.73E+08	8.23	NA
	10 minutes	4.64E+07	7.67	0.57
	30 minutes	6.29E+05	5.79	2.44
	45 minutes	4.27E+04	4.61	3.63

CFU = Colony Forming Unit

TABLE 5: TEST RESULTS

Organism	Timepoint	Average CFU/m ³	Average Log/m ³	Log ₁₀ Reduction vs. Time Zero	Normalized Log ₁₀ Reduction
<i>Staphylococcus aureus</i> (ATCC 6538)	Time Zero	1.16E+08	8.07	N/A	
	10 minutes	*3.20E+02	2.51	5.56	4.99
	30 minutes	*3.20E+02	2.51	5.56	3.12
	45 minutes	*3.20E+02	2.51	5.56	1.93

*No organism recovered. Represents test Limit of Detection.

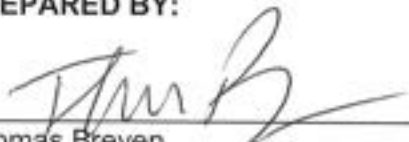
CONTROL RESULTS

The results of controls performed for neutralization confirmation, background contamination, organism purity, inoculum count, and neutralization subculture medium sterility were all acceptable.

CONCLUSION

VigorOx Liquid Sanitizer and Disinfectant (17622C1420) diluted 19.2 oz/108.8 oz defined as 19.2 oz of test substance + 108.8 oz sterile deionized water, applied using the V2 Fog Tank demonstrated a 4.99 log₁₀ reduction of *Staphylococcus aureus* (ATCC 6538) following a 10 minute exposure time when compared to the corresponding baseline result in the presence of a Tri-Part soil organic soil load.

PREPARED BY:


Thomas Breyen
Senior Virologist

5/31/23
Date

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